U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response

Funding Opportunity Announcement and Cooperative Agreement Application Instructions

Funding Opportunity Title: The Biomedical Advanced Research and Development Authority Special Projects

Funding Opportunity Number: EP-IDS-15-002

Catalog of Federal Domestic Assistance (CFDA) Number: 93.360

Technical Assistance Conference Call July 17, 2015, 11:00 am – 12:00 pm US EST
1 (866) 423-3634 Code: 1401352

Application Deadline Date: September 4, 2015 at 11:59 pm EST

Issuance Date: July 6, 2015

FY 2015

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U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
Biomedical Advanced Research and Development Authority (BARDA)

Announcement Type: New

Funding Opportunity Number: EP-IDS-15-002

Catalog of Federal Domestic Assistance (CFDA) Number: 93.360
Biomedical Advanced Research and Development Authority (BARDA), Biodefense Medical Countermeasure Development

Dates: All applications must be submitted via Grant.gov by**: September 4, 2015 at 11:59 PM EST**

I. FUNDING OPPORTUNITY DESCRIPTION

Statutory Authority

Section 319L of the Public Health Service Act (42 U.S.C. 247d-7e).

Summary and Project Overview:

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), supports advanced development and availability of medical countermeasures (MCMs) for chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases through advanced product development, stockpile acquisition, building manufacturing infrastructure, and product innovation. BARDA establishes and maintains business collaborations by means of grants, cooperative agreements, contracts, and other transactions with the public and private sectors, domestically and internationally.

BARDA has grown significantly since inception, acquiring new capabilities and employing new business approaches leading to unprecedented success in the development and acquisition of MCMs. Twenty-one products supported by BARDA have received FDA approval, licensure or clearance against the threats within BARDA's purview and twelve products have been procured under Project BioShield for the Strategic National Stockpile. BARDA has also played a key role in responding to newly emerging threats, including most prominently the 2009-H1N1 influenza pandemic as well as the ongoing Ebola epidemic in West Africa. The *National Strategy for Combating Antibiotic Resistant Bacteria* (2014) identifies BARDA as having a key role in the nation's response to the more slowly, but inexorably emerging threat of antimicrobial resistance (AMR).

By their unpredictability and potentially explosive nature, emerging threats present unique challenges, particularly with respect to the development of MCMs, which normally takes years, requires substantial investment, and is associated with high rates of attrition. Many of the challenges are technical; some are economic. The problem of AMR presents special hurdles in that the discovery of novel drug targets unique to the resistant pathogens has proved increasingly difficult. Having a mechanism in place to engage external subject matter experts and develop far-reaching,

but focused, technical reports that provide recommendations on how to address such challenges would facilitate progress in the development of MCMs against these national health security threats.

There are a limited number of MCMs available today to treat or prevent a number of emerging infectious diseases. In addition, rising resistance rates are reducing the number of therapeutic options available for common infections once considered very treatable. The work performed under this cooperative agreement will directly benefit the public in that it is meant to facilitate and expedite the development of novel MCMs to address a rising unmet medical need.

In order to inform the agency's strategic direction and business practices, BARDA has a need to conduct special projects and develop focused technical reports which may include:

- Objective 1: An expert review and analysis of the potential role of nontraditional antibacterial therapies (mAbs, immunomodulatory and other host directed approaches, phage, microbiome-oriented, etc.) in addressing the threat of antimicrobial resistance and the technical and regulatory challenges facing the development of such products.

- Objective 2: Expert assessment of financial incentives and business models that could support MCM development for emerging infectious diseases, given the unpredictable incidence of such diseases, uncertainties concerning the threat they pose, and limited commercial markets for MCMs against them.

Performance of these tasks may include face to face meetings with BARDA in the DC area, expert interviews, literature reviews, assembling teams of experts for workshops, and preparing final reports with findings and recommendations that will inform BARDA's strategic direction.

Under this award, BARDA may request completion of tasks such as the following:

Objective 1: An expert review and analysis of the potential role of nontraditional antibacterial therapies (mAbs, immunomodulatory and other host directed approaches, phage, microbiome-oriented, etc.) in addressing the threat of antimicrobial resistance and the technical and regulatory challenges facing the development of such products.

An emerging public health crisis now exists as a result of increasing rates of antibiotic resistance at a time when the number of pharmaceutical companies engaged in antibiotic development has declined. Antibiotic resistant (AR) infections are a global problem and are increasing in frequency, leading to increased mortality and health care costs. Unfortunately, the antibiotic development pipeline does not currently contain a sufficient number of therapeutics to keep up with the pace at which AR infections are emerging. In recent decades, drug developers have shifted their focus away from antibiotic development, resulting in a profound development gap. Illustrative of this trend is the fact that no antibiotics with novel mechanisms of action against Gram negative infections have been approved in 40 years.

Historically, industry has focused on generating small molecule drugs that slow or clear infections by inhibiting a key enzyme or pathway required for bacterial survival or virulence. Under selective pressure, bacteria have responded by developing mechanisms of resistance that have become increasingly prevalent, resulting in an "arms race" that we appear to be at risk of losing, with grave consequences for health care and society. Unfortunately, identifying new pathways to target with small-molecule antibiotics has proved challenging and in any case will only result in a new stage of the arms race. Alternative approaches to the management of the problem of antibiotic resistance, some of which are included in the task definition, have been proposed but evidence of clinical efficacy is limited and none have demonstrated effectiveness in reducing the incidence of AR infection or commercial viability in the market.

As part of this task, applicants should be prepared to perform a deep literature review, conduct a workshop of subject matter experts, and prepare a report that:

- Assesses the pipeline of nontraditional antibacterial therapeutics,
- Identifies the barriers, challenges and opportunities related to the development, commercialization, and use of these products, and
- Recommends strategies and initiatives that could be employed to speed the development of these nontraditional therapies.

Objective 2: Expert assessment of financial incentives and business models that could support MCM development for emerging infectious diseases, given the unpredictable incidence of such diseases, uncertainties concerning the threat they pose, and limited commercial markets for MCMs against them.

Emerging infectious diseases (EIDs) present unique challenges with respect to developing MCMs. Some, such as Middle East Respiratory Syndrome (MERS) and Nipah virus, are still quite rare and thus do not present an attractive commercial opportunity to the private sector, resulting in limited (if any) spontaneous investment in the development of MCMs against them. The recent Ebola epidemic, however, has demonstrated the potential of such diseases to increase significantly in incidence and cause massive disruption without a great deal of warning. Other infectious agents, such as Chikungunya virus or West Nile virus, may have substantial impact in certain regions of the world and then appear suddenly and explosively in new regions. For the vast majority of such diseases, no approved therapies are available. As a preparedness organization, BARDA has a keen interest in ensuring that therapies will either exist in the marketplace or be at a stage of technical and manufacturing readiness such that the product can be quickly manufactured and distributed to those who need it.

Traditional drug development typically follows a trajectory where product candidates progress through discovery, preclinical, and clinical stages and finally achieve licensure or approval. The product is then sold on the commercial market, with sales of the product allowing the developer to recoup sunk research and development costs and make a profit. MCMs against emerging infectious diseases may require a different business model, however. The performance of statistically powered clinical trials to demonstrate efficacy may not be feasible and there is likely to be a limited or no commercial market for the product unless incidence rates change dramatically. Commercial sales will thus not allow the company to cover their development costs. With biodefense products, U.S. Government procurements for stockpiling purposes have provided an alternative source of revenue to commercial sales, but stockpiling for EIDs that do not pose a specific threat as potential agents of bioterrorism is not currently envisioned.

In light of the regularity with which EID threats have occurred in recent years, BARDA is committed to establishing a new division within its organizational structure specifically committed to the development of MCMs for EIDs. BARDA will adapt the incentives and processes that it has evolved to address CBRN and pandemic influenza threats to support the development of MCMs against EIDs, but the private sector may require additional provisions or incentives before it is willing to assume the opportunity costs of developing such products. Therefore, the overall goal of this Objective is to assess what kinds of business models and incentives may be required for BARDA to achieve its goal of having MCMs either available or in a state of "readiness" such that the product could be very rapidly manufactured and dispensed to patients. These approaches should be cost effective for BARDA while at the same time aimed to attract pharmaceutical/biotech companies to this space.

As part of this task, Applicants should be prepared to take into account: intellectual property rights, regulatory mechanisms by which the product could be made available to patients, the infrastructure required to manufacture the product, the collection of clinical data in an emergency (if needed), and costs to the government as well as our industry partners.

As part of this task, Applicants should be prepared to perform a deep literature review, conduct a workshop of subject matter experts and industry partners, and prepare a report that:

- Assesses the pipeline of candidate MCMs for selected EIDs (MERS-CoV, Nipah, Chikungunya, etc., to be determined in collaboration with BARDA)

- Identifies the barriers, challenges and opportunities related to the development, commercialization, and use of these products, and
- Recommends business models, incentives, strategies, and initiatives that could be employed to speed the development of these and related products.

II. AWARD INFORMATION

Total Estimated Project Cost (FY2015-FY2018): Estimate $500,000 (subject to availability of funding)

Total Funding Amount (FY2015): $200,000

Anticipated Number of Awards: 1

Project Period Length: 3 years

Budget Period Length: 1 year for Objective 1

Ceiling of Individual Award Range for Project Period: $500,000 (subject to availability of funding in future budget years)

Anticipated Start Date: September 28, 2015

Expected Duration of Support: 3 years

Type of Application Sought: Cooperative Agreement

Funding beyond the first year is dependent on availability of appropriated funds in subsequent fiscal years, satisfactory awardee performance, and a decision that continued funding is in the best interest of the Federal Government.

Cooperative Agreement Award

The Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6305, defines the cooperative agreement as similar to a grant in that a thing of value is transferred to a recipient to carry out a public purpose. However, a cooperative agreement is used whenever substantial federal involvement with the recipient during performance is anticipated. The difference between grants and cooperative agreements is the degree of federal programmatic involvement rather than the type of administrative requirements imposed.

The administrative and funding mechanism used for this program will be the cooperative agreement for which substantial ASPR programmatic involvement with awardees is anticipated during the performance period. This award is subject to the awardee(s) and collaborative requirements and responsibilities set forth in the Cooperative Agreement outlined in the program announcement under this funding opportunity and are hereby incorporated by reference as terms and conditions of this award.

ASPR Responsibilities

ASPR/BARDA will be responsible for the review and approval of program activities including, but not limited to, the proposed use of funds and activities to meet the terms and conditions of the award. ASPR/BARDA will also approve timelines and review progress of the program as well as monitor reporting requirements. Progress evaluation will include the development of timelines and milestones and the oversight of proposed activities through semi-annual reports and on-site joint visits with principal investigator / program managers and others in the United States Government (USG) as needed.

HHS – ASPR Activities:

ASPR/BARDA staff collaborator(s) and/or designee(s) activities for this program are as follows:

- Participate in orientation and/or summary update meetings with the grantee(s) on expectations, regulations and key management requirements, as well as reporting requirements, formats and contents.
- Participate in the development, review and approval of the awardee's annual work plan, detailed budget, and monitoring and evaluation plan.
- Meet via teleconference on a monthly basis with the awardee to assess technical and financial progress.
- Participate in periodic site visits to the awardee(s) and provide the awardee(s) with requested input and expert assistance as appropriate.
- Provide awardee with technical assistance and consultation in identification of appropriate resources outside of both the awardee and HHS to support awardee activities.
- Coordinate activities and synergies with the awardee for this FOA with other ASPR/BARDA awardees.
- Work cooperatively with the awardee to assure that all necessary information and progress resulting from this cooperative agreement is provided to APSR/BARDA in a format that will allow the Department of Health and Human Services to assess the continuing benefits and communicate the successes of the cooperative agreement to the general public.
- Meet at minimum twice with the awardee, review progress towards each objective, and assess, review, and validate progress and accomplishments, and revise work plans as necessary. Collaborate with the awardee on designing and implementing the activities listed above, including, but not limited to the provision of technical assistance to develop program activities, participation on expert assessment panels (as appropriate) the presentation and possibly publication of program results and findings, and the management and tracking of finances related to the projects in conjunction with ASPR.

Awardee Responsibilities

The awardee has the primary authority and responsibility for defining objectives and approaches for planning, conducting, analyzing, publishing results and interpreting project outcomes. The awardee will retain custody of and primary rights to any data developed under this award, subject to US Government rights of access consistent with U.S. law and current Department of Health and Human Services (HHS) and Public Health Service (PHS) regulations and policies.

Awardee will be responsible for coordinating activities approved under the award. The awardee will be responsible for developing achievable program plans. The awardee will also be responsible for tracking that all activities and processes, follow terms and conditions of the grant, and satisfactorily adhere to budget and Monitoring and Evaluation (M&E) reporting plans. Awardee will compile program results from subrecipient (contract and subawards, if any) affiliates into consolidated semi-annual and annual reports.

The awardee will be responsible for planning and participating collaboratively with ASPR/BARDA under this cooperative agreement. Through participation in monthly conference calls, the awardee will work with ASPR/BARDA staff collaborator(s) and/or designee(s) in order to make progress toward its goal of performing the special projects above.

The following is a summary of the cooperative agreement's annual program requirements for awardees:

- Submit all required funding application components, including project narratives, work plans, milestones, and budgets as outlined in Section IV.
- Submit required technical reports, progress reports and program and financial data.
- Ensure that technical data from both the awardee and any possible "subrecipients" necessary to evaluate the progress of the program are available to BARDA.
- Have in place fiscal and programmatic systems to document accountability and improvement.

III. ELIGIBILITY INFORMATION

- Eligible applicants that can apply for this funding opportunity are listed below:
- Nonprofit with 501C3 IRS status (other than institution of higher education)
- Nonprofit without 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)
- Non-domestic (non-U.S.) entity - Unless the authorizing legislation under which an award would be made specifically authorizes awards to foreign entities or the grant is for research (not research-related grants), foreign entities are not eligible for HHS grants

Cost Sharing or Matching:

- There is no cost sharing or match requirement for this project.

Mandatory Meetings:

If awarded, grantee is required to attend a kick-off meeting in Washington DC.

Screening and Responsiveness Criteria

Application Screening Criteria

Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via http://www.grants.gov by **September 4, 2015 at 11:59 PM Eastern Time**.

   If applicant is providing a letter of intent, it must be submitted electronically to Dr. Melissa Stundick at Melissa.Stundick@hhs.gov by **July 13, 2015 at 5:00 PM US Eastern Time**

   A Technical Assistance Conference Call will be held on **July 17 2015 11:00 am – 12:00 pm US Eastern Time** 1-866-423-3634 Code: 1401352

2. The Project Narrative section of the Application must be **double-spaced**, on 8 ½" x 11" plain white paper with **1" margins** on both sides, and a **font size of not less than 11**.

3. **The Project Narrative must not exceed 30 pages**. NOTE: The Project Work Plan, Letters of Commitment, budget narrative and justification forms, Vitae of Key Project Personnel and Other Relevant Annexes **are not counted** as part of the Project Narrative for purposes of the 30-page limit.

Application Responsiveness Criteria

Applications that do not meet the following responsiveness criteria will be administratively eliminated and will not be reviewed:

- Applications submitted after the due date and time will not be reviewed.
- Applications submitted by non-eligible entities will not be reviewed.
- Applications submitted by individuals will not be reviewed.
- Applications failing to include the required forms will not be reviewed.
- ASPR will not accept applications with a Project Narrative that exceeds 30 pages. NOTE: The Project Work Plan, Letters of Commitment, budget narrative and justification forms, Vitae of Key Project Personnel and Other Relevant Annexes **are not counted** as part of the Project Narrative for purposes of the 30-page limit.

IV. APPLICATION AND SUBMISSION INFORMATION

Application Package

Application materials can be obtained from http://www.grants.gov. You must register with grants.gov prior to submitting an application. Applicants previously registered must assure that the registration is still valid and up-to-date. Registration and re-registration may take up to 10 working days to process. Failure to submit the application on time due to late registration will result in ASPR not accepting the application.

Applicants are strongly encouraged to send a letter of intent to the program office by July 13, 2015, outlining the project abstract and approximate funding request. Letters of intent should be sent by email to the attention of Dr. Melissa Stundick at Melissa.Stundick@hhs.gov

Applications must be submitted electronically through grants.gov by the application deadline of **September 4, 2015 at 11:00 PM Eastern Time**. ASPR will not accept any applications that are not submitted electronically via grants.gov.

Grants.gov (http://www.grants.gov) will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in http://www.grants.gov. After ASPR retrieves your application form from http://www.grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by http://www.grants.gov.

Required registrations:

Central Contractor Registration (CCR) and Data Universal Numbering System (DUNS) Requirements:

Except for those entities exempt from requirements listed at 2 CFR Part 25 (e.g., individuals), effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive Federal grant funds from any HHS Operating/Staff Division (OPDIV) or receive sub-awards directly from recipients of those grant funds to:

Be registered in the CCR prior to submitting an application of plan;

Maintain an active CCR registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV; and

Provide its DUNS number in each application or plan it submits to the OPDIV.

An award cannot be made until an applicant has complied with these requirements. At the time an award is ready to be made, if the intended recipient has not complied with these requirements, ASPR:

May determine that the applicant is not qualified to receive an award; and

May use that determination as a basis for making an award to another applicant.

Additionally, all first-tier sub-award recipients (i.e., direct sub-recipient) must have a DUNS number at the time the sub-award is made.

CCR registration may be made online at https://www.sam.gov/portal/public/SAM/

Content and Form of Application Submission (See section VIII. OTHER INFORMATION)

The following document and sections need to be submitted to ASPR in order to be considered for funding; forms are available on grants.gov within the application package:

Application for Federal Assistance – Standard Form SF 424. By signing the SF 424 the applicant agrees not only to assurances and certification, as described on the form, but to all the requirements for this specific appropriation including, but not limited to, the insurance statement as seen on Attachment E.
Budget Information – Standard Form SF 242A

Assurances (Non-Construction Programs) - Standard Form SF 424B
If human subjects are involved you must complete and submit Attachment G

****Project Narrative****

The Project Narrative must be double-spaced, on 8 ½" x 11" paper with 1" margins on both sides, and a font size of not less than 11. You can use smaller font sizes to fill in the Standard Forms and Sample Formats. ASPR will not accept applications with a Project Narrative for Track 1 that exceeds 30 pages. The Monitoring and Evaluation Plan, Curriculum Vitae of Key Personnel, and other Annexes are not counted as part of the Project Narrative for purposes of the 30-page limit, but all of the other sections noted below are included in the limit.

The components of the Project Narrative counted as part of the page limit include:

Abstract
Goal(s) and Objective(s)
Proposed Approach, Work Plan, and Timeline of Proposed Activities – these plans may be in narrative or chart form (see attachments for suggested formats). Any forms submitted to meet this required section will be counted as part of the page limitation.
Evaluation Plan – these plans may be in narrative or chart form (see attachments for suggested formats). Any forms submitted to meet this required section will be counted as part of the 30 page limitation.

Any Other Relevant Annexes that do not count toward the page limit include:

Key Personnel CV – only required if new key personnel are part of this project
Letters of Commitment – only required between collaborating agencies
Budget Narrative – see suggested format in attachment section
Self-monitoring plan and contingency activities identified to ensure project completion and funding outlays are completed within the 12 month project period
Other documents, as needed

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether or not the project meets the minimum requirements for grants under sections 301 of the Public Health Service Act. The Project Narrative should provide a clear and concise description of the project. ASPR recommends that the project narrative include the following components.

****Abstract****

This section should include a brief (no more than 265 words maximum) description of the proposed project, including: goal(s), objectives, outcomes, and products to be developed. Detailed instructions for completing the abstract are included in Attachment D of this document.

****Goal and Objectives****

This section should consist of a description of the project's goal(s) and major objectives. Unless the project involves multiple, complex interventions, we recommend you have only one overall goal. The goal and objectives stated in Section 1 "Funding Opportunity Description" are suggestions and the applicant is free to modify, edit or propose other goal and objectives, but they must similarly align with the ones proposed in this Funding Opportunity Announcement.

****Workplan and Timeline of Proposed Activities****

Each proposed grant activity should have clear timelines for execution and completion.
The Project Work Plan should reflect and be consistent with the Project Narrative and Budget and should cover all of the project period. It should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks / action steps that will be pursued to achieve the goal and outcome(s). For each major task / action step, the work plan should identify timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. Please use the Sample Work Plan format included in Attachment C.

****Organizational Capability****

Each application should include an organizational capability statement. The organizational capability statement should describe how the applicant agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work and/or the capabilities it possesses.

This description should cover capabilities of the applicant agency not included elsewhere in the narrative, such as any current or previous relevant experience and/or the record of the project team in producing cogent and useful reports, publications, or other products.

This section should also include a clear delineation of the roles and responsibilities of project staff, consultants and partner organizations, and how they will contribute to achieving the project's objectives and outcomes. It should specify who would have day-to-day responsibility for key tasks such as: leadership of the project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and ASPR. Curriculum vitae for key project personnel should feature in the annexes.

Annexes

****Key Personnel****

Please attach short curriculum vitae for key project staff only (no more than one page). Neither curriculum vitae nor an organizational chart will count towards the narrative page limit. Also include information about any contractual organization(s) that will have a significant role(s) in implementing the project and achieving project goals.

****Letters of Commitment****

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations and agencies in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. For applications submitted electronically via http://www.grants.gov, signed letters of commitment should be scanned and included as attachments. Applicants unable to scan the signed letters of commitment may email them to asprgrants@hhs.gov by the application submission deadline. In your fax, be sure to include the funding opportunity number and your agency name.

****Budget Narrative****

The Budget Narrative/Justification should be provided. The Budget Narrative is used to determine reasonableness and allowability of costs for the project. All of the proposed costs listed, whether supported by federal funds or non-federal match, must be reasonable, necessary to accomplish project objectives, allowable in accordance with applicable federal cost principles, auditable, and incurred during the budget period.

A sample format is included as Attachment B of this Funding Opportunity Announcement. Applicants are encouraged to pay particular attention to Attachment B, which provides an example of the level of detail sought. A combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding, is required. The Budget Narrative should include travel and relevant expenses to attend the awardee meeting in Washington, DC.

A self-monitoring plan and contingency activities should be identified to ensure project completion and funding outlays are completed within the 24 month project period.

Intergovernmental Review
This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

Funding Restrictions

The following activities are not fundable:

- Cost of money is not allowed even if it's in your negotiated rate agreement
- All salaries are capped at the rate of Executive Level II.
- Construction is not allowed.
- To carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- To advocate or promote gun control.
- Funds cannot be used to lobby.
- Pre-award costs are not allowed.
- Lobbying Restrictions: http://www.hhs.gov/grants/grants/grants-policies-regulations/lobbying-restrictions.html

In addition to the restrictions listed above the following funding restriction apply to all foreign entities applying under this application:

- *Continuation of existing projects without expansion or new and innovative approaches*
- *A&R. Major A&R or construction costs are unallowable under foreign grants and domestic grants with foreign components. (unless specifically authorized in legislation)*
- *Customs and import duties. These costs, which include consular fees, customs surtax, value-added taxes, and other related charges, are unallowable under foreign grants and domestic grants with foreign components.*
- *Indirect costs. With the exception of the American University of Beirut, which is not considered a foreign organization, and the World Health Organization, indirect costs will not be reimbursed.*
- *Research patient care costs. Research patient care costs are allowable only in exceptional circumstances as determined by the OPDIV.*

V. APPLICATION REVIEW INFORMATION

1. Criteria

The application will be reviewed using the following criteria. Scores assigned will assist the reviewer in scoring the applications. It is ASPR's practice to fund only those projects that score in the fundable range.

The following scoring system will be used:

1. Project Relevance/Current Needs – 5 points
2. Organizational capacity – 60 points
3. Budget Allocation – 10 points
4. Project Evaluation – 10 points
5. Impact of Project Outcomes – 15 points

Criterion 1. Project Relevance/Current Needs (5 points)

i. Does the application adequately and appropriately describe and document the key problem(s)/condition(s) relevant to the purpose of the funding opportunity? (5 points)

Criterion 2. Organizational Capacity (60 points)

i. Does the applicant organization clearly identify capacity for carrying out the proposed project and evaluation? (15 points)

ii. Is the proposed project director capable of providing both administrative and scientific leadership to the development and implementation of the proposed program? Is there evidence that an appropriate level of effort will be devoted by the program leadership to ensure the program's intended goal? Is the governance and organization structure appropriate for the project? (10 points)

iii. Do the proposed project director, key staff and consultants have the background, experience, and other qualifications required to carry out their designated roles? Do the technical staff/consultants have prior operational experience performing projects of similar scope and complexity? Does the applicant have personnel capable of extensive and ongoing on-site consulting? (10 points)

iv. Are letters from participating organizations included, and do they express the clear commitment and areas of responsibility of those organizations, consistent with the work plan description of their intended roles and contributions? (5 points)

v. Does the organization primarily use in-house staff to fulfill its organization capabilities? If the applicant requires consultants and subcontractors to fulfill technical competencies, are letter of commitments appropriate? (5 points)

vi. Does the applicant provide documentation demonstrating prior experience and capacities in the performance of expert assessments similar to those provided as examples above?

Criterion 3. Budget Allocation (10 points)

i. Is the budget justified with respect to the adequacy and reasonableness of resources requested? Are budget line items clearly delineated and consistent with work plan objectives? (10 points)

Criterion 4. Project Evaluation (10 points)

i. Does the project evaluation reflect a thoughtful and well-designed approach that will be able to successfully measure whether or not the project has achieved its proposed outcomes? Does the plan include the qualitative and/or quantitative methods necessary to reliably measure outcomes? Is the evaluation also designed to capture

"lessons learned" from the previous overall effort that might be of use to others, especially those who might be interested in replicating the project? (10 points)

Criterion 5. Project Impact (20 points)

i. Are the expected project benefits/results clear, realistic, and consistent with the objectives, purpose of the project, and intended public health impact? Are the proposed outcomes quantifiable and measurable, consistent with the definition of a project outcome contained in Attachment D of the Funding Opportunity Announcement? (15 points)

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation. The committee will assess any IRB materials included in the application, including IRB assessment of standard review criteria (1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

If the proposed research involves the use of human data and/or biological specimens, a justification must be provided for the claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resource Sharing Plans

Recipients of grant awards should make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Research partnerships or collaborations with organizations in the affected regions and their specific role and contribution to the conduct of the proposed study should be reflected in the proposed budget.

NOTE: Preference will be given to applications submitted by entities that are based or have significant operations in one of the states, including the District of Columbia, identified as a major disaster area (see eligibility criteria).

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The Notice of Award is the authorizing document from the ASPR authorizing official, the Officer of Grants Management, and the ASPR Office of Financial Planning and Analysis. The Notice of Award will be sent electronically upon successful review of the application. The Notice of Award sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-federal share to be provided (if applicable), and the total project period for which support is contemplated.

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

2. Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 2 CFR 200 (Subparts A through F), 45 CFR Part 75 and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement located at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

The signature of the authorized organizational representative on the application indicates that the organization complies, or intends to comply, with all applicable public policy requirements as listed in Attachment E of this document.

3. Reporting

Applicants funded under this announcement will be required to electronically submit quarterly program progress reports and Federal Financial Reports (FFR) SF-425. Final performance and financial reports are due 90 days after the end of the project period.

Progress Reporting: Applicants funded under this announcement will be required to electronically submit quarterly program progress reports. As part of the progress report, financial information will be reported both per major

category of expense, and by objectives. Grantees will include sub-recipient monitoring activities that were completed during each quarter.

Subaward and Executive Compensation Reporting: Applicants must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements established under OMB guidance at *2 CFR Part 170*, unless they qualify for an exception from the requirements, should they be selected for funding.

Cash Transaction Reporting: Recipients must report cash transaction data using the Federal Financial Report (FFR), SF-425. Recipients will utilize the SF-425 lines 10.a through 10.c to report cash transaction data to the Division of Payment Management. The FFR SF-425 (lines 10.a through 10.c) is due to the Payment Management System 30 days after the end of each calendar quarter. The FFR SF-425 electronic submission and dates for the new quarters will be announced through the Payment Management/SmartLink Payment System's bulletin board. Funds will be frozen if the report is not filed on or before the due date.

Federal Disbursement Reporting: The SF-425 will also be used for reporting of expenditure data to meet ASPR's quarterly financial reporting requirement. All other lines except 10.a through 10.c should be completed.

Tangible Property Report: Awardees will be required to submit an annual (after each 12 month period) Tangible Property Report (SF 428). Final SF 428 reports are due 90 days after the end of the project period.

Annual A-133 Audits: In accordance with the provisions of OMB Circular No. A-133 (Revised, June 27, 2003), "Audits of States, Local Governments, and Non-Profit Organizations," nonfederal entities that expend financial assistance of $500,000 or more in Federal assistance awards will have a single or a program-specific audit conducted for that year. Nonfederal entities that expend less than $500,000 a year in Federal awards are exempt from Federal audit requirements for that year, except as noted in Circular No. A-133. Grantees will be required to audit this program as a major program.

ASPR will closely monitor all grants and, throughout the course of the project, the grantee may be asked to submit additional reports and other documents.

ASPR will conduct a financial and management capability review. Applicants/grantees will be asked to provide financial and management documents to allow ASPR to complete this requirement.

VII. AGENCY CONTACTS

Grants Management Officer:
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
Washington, DC 20201
Attn: Brenda Cox
Telephone: (202) 809-4144, e-mail: brenda.cox@hhs.gov

Project Officer:
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
Washington, DC 20201
Attn: Dr. Melissa Stundick
Telephone: 202-205-7479 e-mail: Melissa.Stundick@hhs.gov

VIII. OTHER INFORMATION

Review and Selection Process Proposals will be reviewed and evaluated by a panel of subject matter experts that are either federal employees of, or consultants to, BARDA. Proposals will be scored based on the Application Review Criteria listed in Section V. above. The two proposals with the highest technical scores will be further evaluated based cost. The review and selection process permits tradeoffs among cost or price and non-cost factors and allows the Government to award to other than the lowest priced proposal or other than the highest technically rated Applicant. The Applicant that represents the best value to the Government will be invited into negotiations. If negotiations are successful, the Government will make an award to the Applicant that represents the best value to the Government.

Application Elements

a. SF 424 – Application for Federal Assistance

b. SF 424A – Budget Information

c. Separate Budget Narrative/Justification

d. SF 424B – Assurances

e. Lobbying Certification.

f. Proof of non-profit status, if applicable

g. Copy of the applicant's most recent indirect cost agreement, if requesting indirect costs. Upon issuing a contract or sub-award, copies of their indirect cost agreements must be forwarded to the Division of Grants.

h. Project Narrative with Work Plan

i. Organizational Capability Statement and Vitae for Key Project Personnel.

j. Letters of Commitment from Key Partners.

Attachment A: Instructions for Completing Required Forms
(SF 424, Budget (SF 424A), Budget Narrative/Justification)

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. ASPR does not require all the information on these Standard Forms. Accordingly, please use the instructions below in lieu of the standard instructions attached to SF 424 and 424A to complete these forms.

a. Standard Form 424

1. **Type of Submission:** (Required): Application

2. **Type of Application**: (Required) New

3. **Date Received:** Leave this field blank.

4. **Applicant Identifier**: Leave this field blank

5a **Federal Entity Identifier**: Leave this field blank

5b. **Federal Award Identifier**: Leave this field blank

6. **Date Received by State:** Leave this field blank.

7. **State Application Identifier:** Leave this field blank.

8. **Applicant Information**: Enter the following in accordance with agency instructions:

   a. **Legal Name**: (Required): Enter the name that the organization has registered with the Central Contractor Registry.

b. Employer/Taxpayer Number (EIN/TIN): (Required): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service.

c. Organizational DUNS: (Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet.

d. Address: (Required) Enter the complete address including the county.

e. Organizational Unit: Enter the name of the primary organizational unit (and department or division, if applicable**)** that will undertake the project.

f. Name and contact information of person to be contacted on matters involving this application: Complete

9. **Type of Applicant:** (Required) Select the applicant organization "type" from the drop down list.

10. **Name of Federal Agency**: (Required) Enter U.S. Assistant Secretary for Preparedness and Response

11. **Catalog Of Federal Domestic Assistance Number/Title:** 93.095

12. **Funding Opportunity Number/Title:** (Required)

13. **Competition Identification Number/Title:** Leave this field blank.

14. **Areas Affected By Project:** List the largest political entity affected (cities, counties, state etc).

15. **Descriptive Title of Applicant's Project:** (Required) Enter a brief descriptive title of the project.

16. **Congressional Districts Of**: (Required) **16a**. Enter the applicant's Congressional District, and **16b.** Enter all district(s) affected by the program or project. Enter in the format: 2 characters State Abbreviation – 3 characters District Number, e.g., CA-005 for California 5th district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all.

17. **Proposed Project Start and End Dates**: (Required)

18. **Estimated Funding:** (Required) Enter the amount requested.

19. **Is Application Subject to Review by State Under Executive Order 12372 Process?** Check appropriate box

20. **Is the Applicant Delinquent on any Federal Debt?** (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

21. **Authorized Representative**: (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required) title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

b. Standard Form 424A

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this ASPR program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a one year budget.

Section A - Budget Summary
Line 5: Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total non-Federal costs (including third party in-kind contributions and any program income to be used as part of the Awardee match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B - Budget Categories
Column 3: Enter the breakdown of how you plan to use the Federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-Federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.
Line 6a: **Personnel**: Enter total costs of salaries and wages of applicant/Awardee staff. Do not include the costs of consultants, which should be included under 6h - Other.

Line 6b: **Fringe Benefits**: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate.

Line 6c: **Travel**: Enter total costs of all travel (local and non-local) for staff on the project. NEW: Local travel is considered under this cost item not under Other.
Local transportation (all travel which does not require per diem is considered local travel). Do not enter costs for consultant's travel - this should be included in line 6h.

Line 6d: **Equipment**: Enter the total costs of all equipment to be acquired by the project. For all Awardees, "equipment" is non-expendable tangible personal property having a useful life of more than one year and an acquisition cost of $5,000 or more *per unit*. If the item does not meet the $5,000 threshold, include it in your budget under Supplies, line 6e.

Line 6e: **Supplies**: Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d.

Line 6f: **Contractual**: Regardless of the dollar value of any contract, you must follow your established policies and procedures for procurements and meet the minimum standards established in the Code of Federal Regulations (CFR's) mentioned below. Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.). Note: The 33% provision has been removed and line item budget detail is not required as long as you meet the established procurement standards. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line.

Line 6g: **Construction**: Leave blank since construction is not an allowable costs for this program.

Line 6h: **Other**: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits),non-contractual fees and travel paid directly to *individual* consultants, postage, space and equipment rentals/lease, printing and publication, computer use, training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs.

Line 6i: **Total Direct Charges**: Show the totals of Lines 6a through 6h.

Line 6j: **Indirect Charges**: Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. **State governments should enter the amount of indirect costs determined in accordance with DHHS requirements.** An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. Indirect Costs can only be claimed on Federal funds, more specifically, they are to only be claimed on

the Federal share of your direct costs. Any unused portion of the Awardee's eligible Indirect Cost amount that are not claimed on the Federal share of direct charges can be claimed as un-reimbursed indirect charges, and that portion can be used towards meeting the recipient match.

NOTE: **If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-Awardees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.**

Line 6k: **Total**: Enter the total amounts of Lines 6i and 6j.

Line 7: **Program Income**: As appropriate, include the estimated amount of income, if any, you expect to be generated from this project that you wish to designate as match (equal to the amount shown for Item 15(f) on Form 424). **Note:** Any program income indicated at the bottom of Section B and for item 15(f) on the face sheet of Form 424 will be included as part of non-Federal match and will be subject to the rules for documenting completion of this pledge. If program income is expected, but is not needed to achieve matching funds, **do not** include that portion here or on Item 15(f) of the Form 424 face sheet. Any anticipated program income that will not be applied as Awardee match should be described in the Level of Effort section of the Program Narrative.

Section C - Non-Federal Resources
Line 12: Enter the amounts of non-Federal resources that will be used in carrying out the proposed project, by source (Applicant; State; Other) and enter the total amount in Column (e). Keep in mind that if the match requirement is not met, Federal dollars may be reduced.

Section D - Forecasted Cash Needs - Not applicable.

Section E - Budget Estimate of Federal Funds Needed for Balance of the Project

Line 20: Section E is relevant for multi-year grant applications, where the project period is 24 months or longer. This section does not apply to grant awards where the project period is less than 17 months.

Section F - Other Budget Information

Line 22: Indirect Charges: Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

Line 23: Remarks: Provide any other comments deemed necessary.

c. Standard Form 424B - Assurances
This form contains assurances required of applicants under the discretionary funds programs administered by the Assistant Secretary for Preparedness and Response. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. Certification Regarding Lobbying
This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

Proof of Non-Profit Status

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency. This is optional for applicants that have not included indirect costs in their budgets.

Attachment B: Budget Narrative/Justification – Page 1 – Sample Format

The Budget Summary is used to determine reasonableness and allowability of costs for the project. All of the proposed costs listed, whether supported by Federal funds or non-Federal match, must be reasonable, necessary to accomplish project objectives, allowable in accordance with applicable Federal cost principles, auditable, and incurred during the budget period.

Non-Federal Match: (include when grant requires the match/cost sharing)
Matching funds provide support for the purpose and goals of this proposal and enhance the Federal budget request. Applicant is required to provide a detailed listing of all match used to meet the match requirement. In the narrative justification sections describe how the funds support the project and enhance the Federal budget.

All funding used for match must be documented in the same manner as Federal funds. All match funds must follow the same cost principles and regulations that are used for Federal funds – to count as match you must be able to use Federal funds to purchase the item.

An allowable project cost is a cost that is:

- Necessary for the performance of the award.
- Allocable to the project.
- In conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost.
- Consistent with the recipient's regulations, policies, and procedures which are applied uniformly to both Federally-supported and other activities of the organization.
- Accorded consistent treatment as a direct or indirect cost.
- Determined in accordance with generally accepted accounting principles.
- Not included as a cost in any other Federally-supported award.

The following four tests are used in determining the allowability of costs:

- **Reasonableness (including necessity)**. A cost is reasonable if it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large, as well as to their organization.

- **Allocability.** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable if it is incurred solely to advance work under the grant; it benefits both the grant and other work of the organization, including other grant-supported projects or programs; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant.

- **Consistency.** Recipients must be consistent in assigning costs to cost objectives. Regulations regarding cost assignment must be consistent for all work of the organization under similar circumstances, regardless of the source of funding, to avoid duplicate charges.

- **Conformance.** Conformance with limitations and exclusions contained in the Terms and Conditions of award, including those in the cost principles, may vary by the type of activity, the type of recipient, and other characteristics of individual awards.

Budget Summary
(only include section for Non-Federal Match if required by the application)

Section A: Personnel - An employee of the applying agency whose work is tied to the application. Proposed salaries must be reasonable. Compensation paid for employees must be reasonable and consistent with that paid for similar work within the applicant's organization and similar positions in the industry.
Non-Federal Match: Separately list all personnel that will be working on the project and whose time and effort will be used to meet the non-Federal Match requirement. Personnel used as match must be documented through signed time cards and payroll documents. List the source of the match – i.e. State funds.

Table 1: Personnel

Position	Name	Annual Salary/Rate	Level of Effort	Federal Cost	Match
Project Director	Susan Jones	$45,000/year	100%	$45,000	
Project Coordinator	Brad Smith	$42,000/year	50%	$21,000	
			TOTAL	$66,000	

NARRATIVE JUSTIFICAITON: Enter a description of the personnel funds requested and how their use will support the purpose and goals of this proposal. Describe the role, responsibilities, and unique qualifications of each position.

B. Fringe Benefits: Fringe benefits may include contributions for items such as social security, employee insurance, and pension plans. Only those benefits not included in an organization's indirect cost pool may be shown as direct costs. If fringe benefits are not computed as a percentage of salary (i.e. 25%), list all components of the fringe benefits rate, for example:

Non-Federal Match: List for all personnel shown in table 1 under the match section. Match documentation includes payroll records and pay slips. List the source of the match – i.e. State funds.

Table 2: Fringe Benefits

Component	Rate	Wage	Federal Cost	Match
FICA	7.65%	66,000	$5,049	
Insurance	5%	66,000	$3,300	
		TOTAL	$8,349	

NARRATIVE JUSTIFICATION: Enter a description of the fringe funds requested and how the rate was determined.

C. Travel: Federal funds requested for travel are for staff travel only (travel for consultants is listed in consultant category). Travel for other participants, committee members, etc. should be listed under the cost category "other". Applicants are to use the lowest available commercial fares for coach or equivalent accommodations. Note that Applicants will be expected to follow Federal travel policies found at http://www.gsa.gov.
Non-Federal Match: The travel costs must be documented through travel authorizations and paid vouchers. Local travel should be documented by miles traveled. List the source of the match – i.e. State funds.

Table 3: Travel

Purpose of Travel	Location	Item	Rate	Federal Cost	Match
Attend awardee meeting	Washington, DC	Air Fare Per Diem Airport Parking Airport Shuttle Hotel	$350 X 4 people $71/day X 4 days X 4 people $10/day X 4 days $28/RT X 4 people $211/night X 3 nights X 4 people **Subtotal**	$1,400 $1,136 $40 $112 $2532 **$4,120**	
Local travel	Various	POV	.44/mile X 2,000 miles/year	$880	
			TOTAL	$5,000	

NARRATIVE JUSTIFICATION: Explain the purpose for all travel and how costs were determined. List any required travel, funds for local travel that are needed to attend local meetings, project activities, and training events. Local travel rate should be based on agency's personally owned vehicle (POV) reimbursement rate, which should correspond with the GSA rate found at http://www.gsa.gov.

D. Equipment: Permanent equipment is defined as tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more. If the applying agency defines "equipment" at a different rate, then follow the applying agency's policy. In the case of vehicles, etc. applicant should justify purchase rather than rental. If equipment is used by several different projects, you may only charge a percentage of the costs for the purchase based on the amount of time, etc. that the equipment will be used for this grant program. Any purchased equipments must be inventoried according to the guidelines in the HHS Grants Policy Statement.
Non-Federal Match: Enter a description of the equipment match provided and how its use will support the purpose and goals of this proposal. Documentation of match should be in inventory and use records. List the source of the match – i.e. State funds.

Table 4: Equipment

Item(s)	Rate	Federal Cost	Match
Computer Work Station	$5,500 X 2	$11,000	
Computer	$6,000 X .5FTE	$3,000	

Item(s)	Rate	Federal Cost	Match
	TOTAL	$ 14,000	

NARRATIVE JUSTIFICATION: Enter a description of the equipment and how its purchase will support the purpose and goals of this proposal.

E. Supplies: Materials costing less than $5,000 per unit and often having one-time use, for example – general office supplies, postage, printers, etc.

Non-Federal Match: Please note that items such as computers, desks, and projection equipment may be counted as match only once throughout the life of the project. Documentation includes invoices and donation records**.** List the source of the match – i.e. State funds.

Table 5: Supplies

Item(s)	Rate	Federal Cost	Match
General Office Supplies	$50/month X 4 FTE	$200	
	TOTAL	$200	

NARRATIVE JUSTIFICATION: Enter a description of the supplies requested and how their purchase will support the purpose and goals of this proposal. Rates for office supplies, etc. may be based on average monthly costs, FTE, etc.

F. Contracts and Consultants: An arrangement to carry out a portion of the programmatic effort by a third-party or for the acquisition of goods or services is allowed under the grant. Such arrangements may be in the form of sub awards (grants) or contracts. A consultant is a non-employee retained to provide advice and expertise in a specific program area for a fee. List each contract, consultant or sub award separately and provide an itemization of the costs. If a contractor is to be determined, provide a best estimate as to costs for the goods or services to be purchased.

The awardee must establish written procurement policies and procedures that are consistently applied. All procurement transactions are required to be conducted in a manner to provide to the maximum extent practical, open and free competition. The awardee should be alert to organizational conflicts of interest as well as to noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

Method of Selection: This will be sole source, competition, or grant.

Scope of Work: Provide a breakout of the goods and/or services being provided by the contractor. If personnel are being charged then should list name, position, hours and rate/hour. Goods will be listed at number of units and cost/unit. List method to be used for sub-recipient monitoring – site visit, semi-annual reports, etc. Documentation of monitoring should be kept with the contract/award file.

Non-Federal Match: Enter any contracts, etc. that are being used to meet this requirement. When making a contract, a portion may be "donated" to this project by the contracted organizations and should be so noted in the contractual agreement (i.e.: Media outlets may give one free ad for each purchased). If this arrangement has been reached, it

should be noted in the justification section. Documentation includes copies of contractual agreements, payment and donation records.

Table 6: Contract/Sub award

Activity	Name	Method of Selection	Scope of Work	Federal Cost	Match
Public Information	WMTV	Sole source	Paid Ads 12/month X $250/ad X 6 mo. Paid Ads 12/month X $250/ad X 6 mo **Monitoring:** semi-annual report	$18,000	$18,000
Mobil Medical Assets	To Be Determined	Competition	Medical supply inventory ($1,600) Wheelchair bus conversions(6 X $37,000) **Monitoring:** semi-annual report	$223,600	
			TOTAL	$ 241,600	$18,000

NARRATIVE JUSTIFICATION: Provide information as to how the contracted services or goods will enhance the project goals and objectives. Provide sole source justification.

Table 7: Consultant

Organization	Name	Number of Days	Rates	Federal Cost	Match
Trepid	Jon Smith	20	$150/day Travel 4 trips X 1,204 (travel @ $475; lodging @ $175/night X 3; Per Diem @ $51 x4) = $4,816	$ 7,816	
			TOTAL	$ 7,816	

NARRATIVE JUSTIFICATION: Provide information as to how the consultant services or goods will enhance the project goals and objectives.

G. Other:

Expenses not covered in any of the previous budget categories. If rent is requested (direct or indirect), provide the name of the owner(s) of the space/facility. If anyone related to the project owns the building which is less than an arm's length arrangement, provide cost of ownership/use allowance calculations.

Non-Federal Match: Break down costs into cost/unit (e.g., cost/square foot) and explain the use of each item requested. Documentation includes donation, usage, transaction and/or payment records. List the source of match funds – i.e. State funds.

Table 8: Other

Item	Rate	Federal Cost	Match
Postage	$65/mo. X 4 FTE	$3,120	
	TOTAL	$3,120	

NARRATIVE JUSTIFICATION: Explain the need for each item and how it will support the purpose and goals of this proposal. Break down costs into cost/unit (e.g., cost/square foot or cost/month or cost/FTE).

H. Indirect Costs:

Also known as "facilities and administrative costs", indirect costs are costs that cannot be specifically identified with a particular project, program, or activity, but are necessary to the operation of the organization (i.e., overhead). Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that are usually treated as indirect costs. The organization must not include costs associated with its indirect rate as direct costs. If indirect costs are claimed, applicant is to submit a copy of a current negotiated indirect cost rate agreement. Indirect costs are only charged on the items cited in the indirect cost rate agreement (i.e. – personnel and fringe, subawards over $25,000).

Non-Federal Match: Unclaimed indirect costs for costs incurred by using the Federal funds may be used to meet the match requirement. Indirect costs may be charged on the appropriate costs listed in the match categories that are provided by the applicant agency. Documentation should be included in the accounting records of the applicant agency.

Table 9: Indirect costs

Total Direct Cost applied to Indirect Cost	Indirect Cost Rate	Federal Cost	Match
$450,000	22%	$99,000	
	TOTAL	$99,000	

I. FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Table 10: FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Provide a summary of the year one proposed costs (both direct and indirect). Provide the best estimate of the funding that will be needed for each of the years to complete the total project period (for HPP 4 years).

* **FUNDING REQUESTED FOR YEARS 2 THROUGH 4 (if applicable)**

1. Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.

2. If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policies and procedures that state all employees within the organization will receive a COLA.

Attachment C: Project Work Plan, Page 1 – Sample Template

Goal:

Measurable Outcome(s):

* **Time Frame** (Start/End Dates by Month in Project Cycle)

Major Objectives	Key Tasks	Lead Person	1*	2*	3*	4*	5*	6*	7*	8*	9*	10*	11*	12*
1.														

Add as many pages as needed

Attachment D: Instructions for Completing the Project Summary/Abstract

- All applications for grant funding must include a Summary/Abstract that concisely describes the proposed project. It should be written for the general public.
- To ensure uniformity, please limit the length to no more than 265 words on a single page with a font size of not less than 11, doubled-spaced.
- The abstract must include the project's goal(s), objectives, overall approach (including target population and significant partnerships), anticipated outcomes, products, and duration. The following are very simple descriptions of these terms, and a sample Compendium abstract.

  Goal(s) – broad, overall purpose, usually in a mission statement, i.e. what you want to do, where you want to be

  Objective(s) – narrow, more specific, identifiable or measurable steps toward a goal. Part of the planning process or sequence (the "how"). Specific performances which will result in the attainment of a goal.

  Outcomes - measurable results of a project. Positive benefits or negative changes, or measurable characteristics that occur as a result of an organization's or program's activities. (outcomes are the end-point)

  Products – materials, deliverables.

- A model abstract/summary is provided below:

The Awardee, Okoboji University, supports this three year Dementia Disease demonstration (DD) project in collaboration with the local Alzheimer's Association and related Dementias groups. The **goal** of the project is to provide comprehensive, coordinated care to individuals with memory concerns and to their caregivers. The approach is to expand the services and to integrate the bio-psycho-social aspects of care. The **objectives** are: 1) to provide dementia specific care, i.e., care management fully integrated into the services provided; 2) to train staff, students and volunteers; 3) to establish a system infrastructure to support services to individuals with early stage dementia and to their caregivers; 4) to develop linkages with community agencies; 5) to expand the assessment and intervention services; 6) to evaluate the impact of the added services; 7) to disseminate project information. The expected **outcomes** of this DD project are: patients will maintain as high a level of mental function and physical functions (thru Yoga) as possible; caregivers will increase ability to cope with changes; and pre and post – project patient evaluation will reflect positive results from expanded and integrated services. The **products** from this project are: a final report, including evaluation results; a website; articles for publication; data on driver assessment and in-home cognitive retraining; abstracts for national conferences.

Attachment E

II. Potentially Applicable Public Policy Requirements

The following table specifies those public policy requirements that may apply to all or a subset of HHS grant programs and awards. The following key applies to use of this table. The "Types of Applicants/Recipients" column indicates applicability by type of entity, the "Types of Subrecipients" and "Contractors under grant" columns indicate whether the requirement flows down, as well as applicability by organizational type. An "NA" means it does not flow-down.

Public Policy Mandates or Encouragements				
Requirement	Applicability	Types of Applicants/ Recipients	Subawards	Contracts for routine goods/services
Age Discrimination Act of 1975	All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
Animal Welfare	Applications and awards for activities involving warm-blooded animals	All	All	All
Ban on Cloning of Human Beings (Presidential memorandum of March 4, 1997)	All awards	All	All	All
Certificates of Confidentiality	Research awards (includes research training in each case specified as "research")	All	All	All
Civil Rights Act of 1964 (Title VI)	All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
Confidentiality of Patient/Client Records	All research awards and awards to substance abuse programs	All	All	All

Drug-Free Workplace	All covered applications and awards	All	NA	NA
Education Amendments of 1972 (Title IX)	All applications from and awards to domestic entities	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations
Financial Conflict of Interest	All applications and awards for research	Does not apply to Phase I of the SBIR/STTR programs and to Federal institutions	All except Federal institutions	NA
Fly America Act/ U.S. Flag Air Carriers	All types of awards	All	All	All
Hatch Act	Awards to State or local governments	All	All	NA
Health Insurance Portability and Accountability Act (HIPAA)	All awards to covered entities	All covered entities	All covered entities	All covered entities
Historic Preservation/ Archaeological Sites	All awards that include major or minor A&R, construction, or any work that will result in physical changes to real property	All	All (Note: applicability to subrecipients is being considered based on recent litigation)	All
Human Subjects Protections	Research applications and awards	All	All	All
Investigational New Drug Applications/ Investigational Device Exceptions	Research awards	All	All	All

Limited English Proficiency	All types of awards	All	All	NA
Lobbying	Varies depending on source of requirement Byrd Anti-Lobbying Amendment applies to all awards expected to exceed $100,000 (except that Indian tribes, tribal organizations, and any other Indian organizations may be exempted from the Byrd Anti-Lobbying Amendment with respect to expenditures specifically permitted by other federal law) Cost principles apply as indicated therein Limitations in 18 U.S.C. 1913 apply to all awards	All consistent with "Applicability"	All consistent with "Applicability"	All consistent with "Applicability"
Military Recruiting and Reserve Officer Training Corps Access	All types of applications and awards	Institutions of higher education	Institutions of higher education	NA
Pro-Children Act	All awards performed in facilities where children are served	All	All	All
Protection of Research Subjects' Identity	All research awards	All	All	All

Public Health Security and Bioterrorism Preparedness and Response Act	All types of awards	All	All	All
Recombinant DNA Molecules and Human Gene Transfer Research	Applications and awards for research	All	All	All
Research Misconduct	Applications and awards for research and research training	All	NA	NA
Research on Transplantation of Human Fetal Tissue	Research awards	All	All	All
Resource Conservation and Recovery Act	All awards to States or agency of a political subdivision of a State (which for this purpose includes State and local institutions of higher education or hospitals)	All	All	All
Seat Belt Use (EO 13043)	All types of awards	All	NA	NA
Smoke-Free Workplace	All awards	All	NA	NA
Standards of Conduct	All types of awards	All	NA	NA
Text Messaging While Driving (EO 13513)	All			
Trafficking in Persons (Trafficking Victims Protection Act, as amended; 2 CFR part 175	All types of awards	Private entities	Private entities	NA

Uniform Relocation Assistance and Real Property Acquisition Policies Act	All awards, but, in particular, those involving acquisition of real property	All	All	NA
USA PATRIOT Act	All types of awards	All	All	All

Attachment G : Research and Related Project Information –

Provide the following information to the related questions

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no.

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with policies covering human subjects research.

1. Are Human Subjects Involved? YES NO

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? **YES** **NO**

Yes: If the project is exempt from Federal regulations, check Yes.

No: If the project is not exempt from Federal regulations, check No.

If yes, **Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.**

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHPR guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). Institutions often designate their IRB to make this determination. Since IRB approval is not required at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. Human subjects research should be designated as exempt if the proposed research meets the criteria for one or more of the six exemptions.

If no, is the IRB review Pending? **YES** **NO**

Enter the latest Institutional Review Board (IRB) approval date. Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle. If IRB is still pending at time of award then affected components of the award will be restricted. Failure to obtain IRB approval within the agreed upon time frame may result in the termination of an award.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 21 on the SF424 declaring that it will comply with 45 CFR part 46 and proceed to obtain a human subjects assurances (see http://www.hhs.gov/ohrp). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

2. Are Vertebrate Animals Used? YES NO

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

2.a. If YES to Vertebrate Animals

Is the Institutional Animal Care and Use Committee (IACUC) review Pending?

YES NO

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending.

Animal Welfare Assurance Number:

Enter the Federally approved assurance number, if available.

To determine if your organization holds an Animal Welfare Assurance, see http://grants.nih.gov/grants/olaw/olaw.htm#assur. Applicants should check "Yes" to the question "Is the IACUC review Pending?" even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle. If the applicant organization does not have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), NIH, enter "None" in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW. If IACC approval is still pending at time of award then affected components of the award will be restricted. Failure to obtain IACC approval within the agreed upon time frame may result in the termination of an award.

3. Is proprietary/privileged information included in the application? YES NO

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation. "

4. Environmental Questions

Most research grants are not expected to individually or cumulatively have a significant effect on the environment, and there are several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific FOA indicates that the National Environmental Policy Act

(NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the line marked "Yes" should be checked and an explanation provided in field 4.b.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does this project have an actual or potential impact on the environment?

YES **NO**

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed? YES NO

4.d. If yes, please explain

Enter additional details about the EA or EIS. If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments** located to the right of Step 11 - Other Attachments.

5. Is the research performance site designated, or eligible to be designated, as a historic place? *YES NO*

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes and then provide an explanation. Otherwise, check the No.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators? YES NO

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no..

Applicants to PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.